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Citation for published version:

Leung, G & Porter, G 2018, 'Malpractice litigation in acute stroke care: Where are we now?', *Medico-Legal Journal*, vol. 86, no. 3, pp. 134-139. <https://doi.org/10.1177/0025817217750494>

Digital Object Identifier (DOI):

[10.1177/0025817217750494](https://doi.org/10.1177/0025817217750494)

Link:

[Link to publication record in Edinburgh Research Explorer](#)

Document Version:

Peer reviewed version

Published In:

Medico-Legal Journal

Publisher Rights Statement:

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Full title:

Malpractice litigation in acute stroke care - *where are we now?*

Short title:

Malpractice litigation in acute stroke care

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28184350.

Funding

This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

Declaration of interest

The authors declared that there is no conflict of interest with respect to the research, authorship, and/or publication of this article.

Abstract

Acute stroke care (ASC) has undergone momentous changes in recent years with the introductions of intravenous thrombolysis, mechanical thrombectomy and integrated stroke services. While these are welcome developments, they also carry unique medico-legal challenges. In 2015, a patient from Greater Manchester was awarded over £1 million in compensation after ambulance paramedics failed to admit her to a specialist unit. This paper explores the medico-legal implications of this first but overlooked thrombolysis-related claim in the United Kingdom. It is submitted that the highly time-dependent and multidisciplinary nature of ASC may expose a host of healthcare personnel, both medical and non-medical, to risks of legal pursuit for failing to provide appropriate care, and that available scientific evidence will likely support such claims. The situation calls for an urgent and concerted effort at implementing improvement measures at national levels. A reminder of the legal consequences of substandard ASC is timely and necessary. (150 words)

Keywords:

Medico-legal; Negligence; Thrombectomy; Thrombolysis; Standard of care; Acute stroke management

Malpractice litigation in acute stroke care – *where are we now?*

Introduction

The introduction of intravenous thrombolysis, mechanical thrombectomy and integrated stroke services have drastically transformed acute stroke care (ASC) in recent years.¹ Around the world, national strategies and clinical guidelines have been formulated that emphasise these approaches. While these are welcome developments, they may also introduce the possibility of related malpractice claims if healthcare professionals deviate from the guidance. Although a number of learned commentaries on the medico-legal aspects of stroke treatment are already available in the literature,²⁻³ medical advances continue to establish new standards and challenge current thinking on what appropriate ASC should be and how various parties along the care pathway may be affected. At the same time, changing public expectations also create new avenues for negligence claims as indicated by the first UK case in 2015 in which a patient was awarded over £1 million in compensation for being taken to the wrong hospital.⁴ This paper aims to explore the medico-legal implications of this over-looked case, and discuss some of the appropriate policy responses that may be required.

Contemporary treatment for acute ischaemic stroke

In acute ischaemic stroke, the interruption of blood supply to the brain by obstructing blood clots can cause rapid cell death, functional loss and significant disabilities. The goal of contemporary ASC is to re-establish brain perfusion as soon as possible. Two treatment modalities are available: intravenous thrombolysis (IVT) and mechanical thrombectomy (MT).

With IVT, the offending blood clot is dissolved pharmacologically. Its clinical efficacy was established in 1995 where IVT resulted in a 32% relative increase in the proportion of patients with minimal or no disability when compared with control.⁵ Subsequent clinical trials demonstrated even more promising findings, with patients [treated](#) within three hours deriving the greatest benefits; those treated later had higher risks of complications.⁶ The routine use of IVT has been approved by national agencies including the United States Food and Drug Administration, and the National Institute for Health and Care Excellence (NICE) in the United Kingdom (UK).⁷ With MT, the obstructing clot is removed mechanically using endovascular catheter-based devices. Its efficacy when used within six hours of symptom-onset is well established especially where IVT is ineffective or contraindicated.⁸ Though a relatively recent development, MT has already been approved by professional bodies in the US, continental Europe, and NICE in the UK.⁹

These momentous developments ushered in a new era of ACS that contrasts sharply with the previous nihilistic approach to ischaemic stroke. Complete functional recovery is now a realistic prospect for many patients. The dramatic benefits of IVT and MT also mean that failure to provide these treatments are likely to be seen as the cause of otherwise avoidable health and socio-economic losses as well as justifiable discontent on the part of the patient. Related malpractice claims could only be expected - and materialised.

The case of Lynne Horner

Worldwide, IVT-related claims have already occurred including 46 in the United States (US) by 2013,³ and six in Taiwan by 2010.¹⁰ The first successful claim in the UK involved Lynne Horner, a 69-year-old woman from Greater Manchester who suffered a stroke in 2010. A rapid response paramedic initially confirmed her symptoms of slurred speech and confusion. An ambulance paramedic, who arrived soon after, thought that she was recovering and decided to take her to a non-specialist hospital instead of the regional stroke centre. By the time she was secondarily transferred to a specialist unit, it was too late for IVT. She sustained permanent paralysis. The North West Ambulance Service NHS Trust admitted negligence, and damages of over £1 million were awarded following a court hearing in 2015.⁴

What is particularly unusual about this case is that it was not emergency or stroke

physicians but ambulance paramedics that were found to be at fault; it also represents the probable worldwide first IVT-related claim that involves failure of direct stroke unit admission. It throws light on how some fundamental elements of medical negligence apply in contemporary ASC - namely, the expansion of duty of care, the legally required standard of care, and the proof of causation. These will be discussed in turn.

The expanding circle of carers

Traditionally, English courts are reluctant to hold emergency service providers such as fire brigades and the police liable in negligence. Claims against ambulance services tended to be uncommon and usually unsuccessful.¹¹ Things changed, and the present case reaffirms the landmark decisions in *Kent v Griffiths* that establishes paramedics owe patients a duty of care once an emergency call has been accepted.¹¹ Since *Kent*, most claims against paramedics involve delays and technical failures; t misdirected hospitalisation, as in the present case, remained unusual.

The highly time-dependent, specialised and multidisciplinary nature of contemporary ASC is likely to expose other healthcare personnel to risks of legal claims. Apart from neurologists, neurosurgeons and emergency physicians, radiographers and radiology assistants now play critical roles in providing rapid and critical clinical investigations; nurse practitioners similarly participate in front-line patient triage. Failure on their part to discharge professional duties can delay diagnosis and treatment, and may be found

negligent. Effective protocol implementation and training are essential and rewarding, if only for better patient care.

Even informal carers could, arguably, be implicated for failure to call for medical help in a responsible manner, in that a person who lacks capacity, as might be the case in stroke, is owed a duty of care by his or her carer to act in that person's best interest.¹² This is an onerous duty since the assessment of the neurological status and mental capacity of a stroke patient can be far from straightforward even for seasoned clinicians. A conscious but agitated patient who refuses hospitalisation, for example, may present family members with significant challenges; the 'diagnosis' of stroke in an elderly patient presenting with slurring of speech is no less difficult. Better public education is needed.

The evolving standard of care

Numerous Clinical Practice Guidelines (CPG) on the use of IVT and MT are available. However, rapid changes in medical technology, constant emergence of new clinical evidence and different approaches in data interpretation have led to discrepancies between available guidance. According to a 2015 review, for example, CPG on the use of IVT at 3-4.5 hours post-symptom-onset may range from "*strong or weak recommendations for*" to "*weak recommendations against*" or "*should not be considered standard of care*". Treatment within three hours is uncontroversial.¹

Mostly issued by eminent professional bodies, these CPG, while without specific legal status, are likely to be used by expert witnesses in formulating their opinions. In the US, where the ‘learned treatise doctrine’ recognises CPG as having authoritative power in establishing the standard of care and being admissible as substantive evidence in court, a number of successful IVT-related claims have already been brought.¹³ In England and Wales and elsewhere, a gradual doctrinal shift towards a greater readiness for the court to appraise and interpret CPG also accords them increasing weight.¹⁴ But since the court is not supposed to prefer one body of opinion to another, discrepancies between CPG may potentially lead to unpredictable and inconsistent judicial outcomes. In medical negligence, doctors are judged by the ‘prevailing’ standard of care, and it can be difficult to ascertain in this context of evolving treatment paradigms what the ‘prevailing’ standard should be at the time when a doctor manages a stroke patient. In this regard, the ambulance service provider’s acceptance of breach of duty in Lynne Horner’s case effectively acknowledges the 2008 NICE guidance that recommends IVT within 4.5 hours, and, importantly, that

“all people with suspected stroke should be admitted directly to a specialist acute stroke unit following initial assessment, either from the community or from the A&E department”.⁷

Whether this will indeed become the legally required standard of care for acute ischaemic stroke is to be confirmed. If so, a duty would arguably require all hospital trusts in England and Wales to fund specialist units of sufficient quality and implement

protocols so that patients can - as far as reasonably possible - be treated within the specified timescale; whatever the day of the week or time of day.

Proof of causation

For a claim to succeed, it must be established that the breach of duty of care has caused the injury at issue. Causation in medical negligence is notoriously difficult to prove and not least in stroke-related claims. In the recent aspirin-related case of *Choudhury*, despite the hospital trust's admission to several counts of breach of duty, a claim against delayed treatment was rejected for unproven causation.¹⁵ The existing legal test requires the proof of a greater than 50% chance (i.e., on the balance of probability) that 'but for' the breach of duty of care, the claimant would not have sustained injury. A 'loss of chance' claim where the probability of good outcome had there been no breach of duty is less than 50% is unlikely to succeed.¹⁶

With IVT, findings from the initial 1995 study would probably defeat any 'loss of chance' claim since the likelihood of good recovery following treatment was not found to exceed 50%; this was indeed the basis of a successful defence in a US case.¹⁷ Subsequent clinical trials, however, demonstrated a greater chance of good outcome if IVT was given within three hours that might support future claims.¹⁸ Indeed, a 2013 systematic review of 'stroke claims' brought in non-UK jurisdictions found that judicial rulings were usually in favour of plaintiffs who argued that IVT would have resulted in a >50% *overall*

chance of improvement, as opposed to defendants' counter-arguments that IVT would only yield a 32% *greater chance* of improvement.³ Although the case of Lynn Horner was not fought out on causation, its outcome suggests that the above could well be the direction of travel in the UK. A similar situation is found with MT where the likelihood of good functional recovery following treatment can be close to 60%.⁹

Even when a claimant fails to establish causation under the traditional 'but for' test, damages may still be awarded if courts apply the alternative 'material contribution' test for causation. To this end, the Privy Council ruling in *Williams* in 2016 provides helpful guidance.¹⁹ It confirms the application of 'material contribution' to cover not only negligence that has materially contributed to *the cause of the injury* sustained (e.g., delayed thrombolysis, in the present context) but also negligence that has materially contributed to *the injury itself* (e.g., prolonged brain ischaemia).

That said, it is important to note that a key factor in *Williams* was that the injury sustained was caused by a single known agent, namely, sepsis from a ruptured appendix, while the situation can be far more complex in acute stroke in that failure of stroke unit admission might only be one of a number of events (e.g., post-thrombolysis haemorrhages, pneumonia) leading up to an adverse outcome. A claim based on 'material contribution' might fail if the injury may have been caused by one or more of a number of disparate factors, one of which was attributable to a wrongful act or omission by the defendant. A detailed discussion on the subtle, yet important, distinction between 'divisible' and 'indivisible' injuries under these situations is beyond the scope of this

paper. It suffices to say that whether or not a defendant would be liable in full would depend on whether it can be established that pre-hospital delay, for example, has contributed to only a specific portion but not all of the injury sustained.

Integrated stroke services and corporate responsibilities

The present case highlights the importance of the provision of ASC under an effective *system of care*. The latter involves the comprehensive integration of multiple elements of care, ranging from the promotion of community awareness to ambulance diversion, secondary transfer arrangement, fast-track triage and treatment delivery at specialist units with adequate equipment and expertise support. It is a resource-intensive, logistically demanding and politically challenging endeavour that calls for considerable will and power. In this regard, the centralisation of ASC in two metropolitan areas in England (i.e., London and Greater Manchester) is a commendable achievement that has been shown to improve clinical and cost outcomes.²⁰ However, different approaches in policy implementation have seen better access to care in London than in Greater Manchester, where Lynne Horner resided. The present case thus provides a strong indication for the evaluation of the current systems of care in terms of stakeholder engagement, implementation strategy, protocol compliance, training and quality assurance. Equitable access to care in other parts of the country, especially remote areas, also needs to be addressed.

A variety of policy responses are possible. In Illinois, US, for example, a 'stroke bill' was signed into law in 2014 whereby a tiered system of hospital network, coupled with ambulance transport protocols, would ensure that patients will be treated at the highest possible level of care available in their area.²¹ In the UK, National Health Service (NHS) England has recently announced plans to set new performance targets for the ambulance service in dealing with 'rapid life-changing care for conditions such as stroke'.²² It adopts a condition-specific approach so that critically ill patients can receive not only expeditious but also the most appropriate form of care. The effectiveness and necessity of these strategies remains to be determined.

The present case of Lynne Horner is unlikely to be a one-off, and the possibility that substandard ACS will give rise to future claims against corporate bodies cannot be over-emphasized. Stroke-related claims are expensive, and future litigation will to the already mounting medico-legal costs to the NHS that can potentially offset any savings from centralisation of services.²³ Civil litigation aside, it is worth remembering that mismanaged stroke can be fatal which raises, at least theoretically, the possibility of gross negligence manslaughter charges brought against hospital trusts under the Corporate Manslaughter and Corporate Homicide Act 2007. Corporate liability might conceivably be found where there is a 'gross breach of duty' in the management and organisation of established and committed stroke services.²⁴ A collective responsibility exists for healthcare providers to implement and strengthen ASC at both policy and clinical levels.

Conclusion

The tragic case of Lynne Horner emphasises how contemporary ASC can be fraught with medico-legal challenges. Although the setting of national strategies and professional guidelines to improve stroke treatment is a positive development, it does, like other guidelines, expose a host of healthcare professionals or even informal carers to risks of negligence litigation when they are not followed. The outcome of the present case and available clinical evidence suggest that prompt provision of IVT and MT may become legally required standards of care, and that the evidence of their efficacy may fulfil the burden of proof of causation in future claims. Effective systems of care must be implemented and should be a top priority within and beyond metropolitan areas within the UK and world-wide.

The need to develop integrated ACS worldwide raises important resource allocation issues; any payouts to litigants will be come out of money used to run national care systems and so increase financial pressures on them. Urgent and concerted efforts are needed to improve matters which should include effective communication of the best treatment regimes to all professionals (e.g. paramedics, general practitioners, emergency physicians), review and updating of Standard Operating Procedures, and education of the wider public. Substandard stroke care is not just disastrous for the patient it may become expensive for its providers.

Acknowledgments

None

Funding

This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

Declaration of interest

The authors declared that there is no conflict of interest with respect to the research, authorship, and/or publication of this article.

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